

Notice of Allowability**Application No.**

10/517,509

Applicant(s)

COELINGH BENNINK ET AL.

Examiner

SAMIRA JEAN-LOUIS

Art Unit

1627

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 11/10/10.
2. ☒ The allowed claim(s) is/are 24,26,28,32 and 33.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: ____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date ____.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date ____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).**
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|--|--|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date <u>09/15/10</u> . |
| 3. <input checked="" type="checkbox"/> Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date <u>10/20/2009, 10/20/2009</u> | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other ____. |

DETAILED ACTION

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Tom Wolski on December 13th, 2010.

The application has been amended as follows:

1. Cancel claims 17, 21-23, 25, 27, and 29-31.

EXAMINER'S STATEMENT OF REASONS FOR ALLOWANCE

Applicant's amendment to the claims filed November 10, 2010 has been fully considered. In light of Applicant's amendment and the Examiner's amendment, claims 24,26, 28, and 32-33 are allowed and renumbered to claims 1-5.

Receipt of Applicant's amended claims is acknowledged and have been entered.

In light of Applicant's amendment, the Examiner's amendment, and Applicant's arguments, the 112, first paragraph is hereby withdrawn.

In light of Applicant's amendment, the Examiner's amendment, and Affidavits, the 103 (a) rejections over Kragie et al. (2004/0192598 A1) in view of Willhite (Pharmacotherapy, 2001, Vol. 21, Issue 4, pgs. 464-480); and over Sitruk-Ware et al. (Shweiz. Rundsch, Med. Praxis, 1997, Vol. 86, No. 33, pgs. 1-13) in view of Spicer (U.S. 5,211,952) and in further view of Willhite et al. (Pharmacotherapy, 2001, Vol. 21, Issue 4, pgs. 464-480) are withdrawn.

The following is an examiner's statement of reasons for allowance: Claims 24, 26, 28, and 32-33 are drawn to a method of treating or reducing a risk of developing vaginal dryness, wherein the method comprises applying to the vaginal epithelium a composition containing estetrol, precursors capable of liberating estetrol; or mixtures of estetrol and precursors; and a cosmetically acceptable vehicle. There is no prior art disclosing the applicant's method of treatment, particularly with estetrol or precursors thereof. The closest arts were Kragie et al. (2004/0192598 A1) in view of Willhite (Pharmacotherapy, 2001, Vol. 21, Issue 4, pgs. 464-480); and Sitruk-Ware et al. (Shweiz. Rundsch, Med. Praxis, 1997, Vol. 86, No. 33, pgs. 1-13) in view of Spicer (U.S. 5,211,952) and in further view of Willhite et al. (Pharmacotherapy, 2001, Vol. 21, Issue 4, pgs. 464-480). Kragie teaches the use of compositions that can replace the role of estrogens in the functions of humans comprising estrogen function replacement

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agent (s) (EFR) that can selectively, partially, or totally replace the function of estrogens and suitable carriers. Examples of such agents include *inter alia* derivatives of estradiol such as estetrol. Likewise, Sitruk-Ware et al. teach that urogenital symptoms is due to low estrogen after menopause and thus suggests the use of estrogens for prolonged release regimen in the treatment of urogenital atrophy. However, the Examiner contends that at the time of the invention (i.e. 2002), estetrol would not have been expected to work well in the aforementioned method since the prior art teaches that estetrol's half-life was expected to be in the range of 5-30 minutes, contrastingly different to what applicant discovered, i.e. a half-life of estetrol of 28 hours in humans. Based on applicant's unexpected results, estetrol can be construed as superior in comparison to other estrogens and thus would not have been obvious to try at the time of the invention in the long list delineated in Kragie and Sitruk-Ware. Since the present claims require the use of estetrol or precursors thereof in the method of claim 28, and Kragie or Sitruk-Ware alone do not render obvious the particular method of claim 28, claims 24, 26, 28, and 32-33 are therefore allowable.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

Claims 24, 26, 28, and 32-33 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samira Jean-Louis whose telephone number is 571-270-3503. The examiner can normally be reached on 7:30-6 PM EST M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. J. L. /

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12/17/2010

/SREENI PADMANABHAN/

Supervisory Patent Examiner, Art Unit 1627